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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Ayres

Application No. 09/887,318

Filed: June 21, 2001

For: A COATED, PLATFORM-GENERATING TABLET

Examiner: Simon J. Oh

Date: July 11, 2003

Art Unit: 1615

CERTIFICATE OF MAILING

I hereby certify that this paper and the documents referred to as being attached or enclosed herewith are being deposited with the United States Postal Service on July 14, 2003, as First Class Mail in an envelope addressed to: MAIL STOP AF, COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.

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DECLARATION BY JAMES W. AYRES PURSUANT TO 37 C.F.R § 1.132

I, James W. Ayres, hereby declare as follows:

1. I currently am a Distinguished Professor of Biopharmaceutics and Pharmacokinetics in the College of Pharmacy at Oregon State University, and a copy of my *curriculum vitae* is attached hereto (Exhibit A). I have authored over eighty peer-reviewed publications, and I am an inventor of several patented technologies, including those described in nine U.S. patents in the pharmaceutical and biotechnology fields.

2. I have reviewed the Office action dated June 3, 2003, concerning patent application No. 09/887,318. I also have reviewed U.S. Patent Number 6,183,780 to Van Balken et al. (Van Balken) and U.S. Patent Number 6,120,803 to Wong et al. (Wong), as cited by the Examiner against this application.

3. At paragraph 3 on page 5, the Office action cites to Van Balken's text at column 5, lines 8–13 for teaching that "sustained-release of a drug is desirable after a predetermined lag time." However, the cited language is taken out of context and the Office action's interpretation contradicts Van Balken's combined teachings and text. Van Balken's formulations are solely

directed to immediate release compositions. The bulk of Van Balken's text from column 4, line 54 through column 5, line 13 explains how prior art coatings, such as those disclosed in U.S. Patent No. 4,798,724 and EP 0655 240, which disclose water-soluble coating materials, are unsuitable for Van Balken's formulations. In the cited section, Van Balken teaches that delayed immediate release is desired, and that the water-soluble coating materials would provide a different release profile, such as sustained release, and are therefore unsuitable. Specifically, Van Balken states at column 4, lines 60–62 that "to prevent release of active substance from the formulation by means of diffusion o[r] permeation, the coating should not comprise substantial amounts of polymeric coating materials that are soluble and/or erodable." Rather than using such water-soluble coating materials, Van Balken uses "water-insoluble coating materials." See, column 4, line 20 (emphasis added). In contrast, claim 1 of the present application features a coating comprising a "water-soluble modifier." Thus, Van Balken expressly states that the presently claimed coating materials comprising water-soluble modifiers are unsuitable for his purposes.

4. Van Balken further discusses other dosage forms that exhibit release via diffusion or permeation rather than Van Balken's desired immediate release profile. For example, at column 5, lines 4–7, Van Balken describes EP 0655 240 as having a coating that is "eroded, leading to an increasing permeability and consequently diffusion of the active substance through the coating." In contrast, when Van Balken's coating is exposed to gastrointestinal fluids as described at column 4, lines 52 and 53, "[o]nly the plasticizer leaks away from the coating." Thus, the Office action has misconstrued Van Balken's text as teaching that sustained release of a drug is desirable. Van Balken actually teaches that sustained release, as apparently would be provided by the coating of EP 0655 240, should be avoided.

5. At page 3 the Office action characterizes Van Balken's core, described at column 3, lines 32-45, as including "a small amount of a swellable material." However, this statement is taken out of context. The Office action ignores the language at column 3, lines 39–43, which states that the composition is chosen in such a way that "an immediate release carrier, having no substantial swelling properties is obtained, which means that the composition of the carrier has no influence on the lag-time of the system." (Emphasis added) Thus, the core composition as a

whole does not swell, despite including a "small amount" of a swellable material. Indeed, at column 3, lines 23–25, Van Balken distinguishes the prior art in that "the core of the present invention does not have swelling properties." Van Balken's core does not swell and Van Balken teaches that the core should not swell. In contrast, rupture of the coating in the presently claimed tablets occurs due to swelling of the tablet contents. See, for example, page 17, lines 13–20 of the present application as filed, which explains that "after sufficient swelling occurs, the polymer film coating ruptures."

6. At page 6, the Office action incorrectly asserts, with reference to Van Balken's Figure 19, that "the remnants of a ruptured coating providing a lag-time in the release of a drug, as disclosed in Van Balken et al., would also likely contribute to the gastric retention of a dosage form arising from the combined disclosure of the prior art." According to Wong's description of the requirements for gastric retention, Van Balken's coating would not contribute to the gastric retention time for at least two reasons. First, the remnants of the ruptured coating are not rigid or semi-rigid, and thus would not resist the compressive force of stomach contractions. See, Wong at column 5, lines 33–39. Second, even if Van Balken's coatings were rigid or semi-rigid, Van Balken's active ingredient does not remain attached to the coating. See, column 4, lines 13–15, "[w]hen the 'cover of the box' has been opened, the active substance is immediately released." See also, Figure 19C, which is described at column 3, lines 10–12, as depicting the "coating left after release of the core containing active substance." Therefore, the coatings used by Van Balken are insufficient to provide substantially lengthened gastric retention times.

7. The Office action states, at page 4, that Wong and Van Balken could be combined "to create a dosage form that ensures gastric retention for an extended period of time." Even if this were true, such a dosage form would not yield the claimed tablet, because the claimed tablet is not retained in the stomach any longer than a conventional dosage form.

8. The Office action indicates at page 4, lines 5–6 that Wong discusses "platform dosage forms." However, Wong uses the term "platform" differently than it is used in the present application. Wong appears to use the term in the sense of providing a platform for delivering any drug, i.e., as used by Wong, platform means "vehicle." However, the term "support

platform" as used in the present application refers to the coating material that remains attached to the tablet following rupture of the coating. Thus, the support platform is generated *in situ*. Furthermore, Wong's coating is highly water soluble, containing materials such as Methocel A 15 LV Premium and sorbitol, both of which are highly water soluble. See, Wong's Example 8, which uses 52 milligrams of a subcoating and 21 milligrams per tablet of an overcoating consisting of 80% Methocel and 20% sorbitol. Because Wong's coatings dissolve rapidly in gastric fluid, the coatings cannot produce a support platform *in situ*.

9. The Office action asserts, at page 6, that Wong "provide[s] for more than one method by which the disclosed dosage form can be retained in the stomach." To support this assertion, the Office action proposes that a "gastric-emptying delaying agent" as disclosed by Wong could be used to coat a tablet, thereby facilitating gastric retention. As noted by Wong, concurrent administration of gastric emptying agents delays expulsion of tablets from the stomach, but this does not suggest combination of Van Balken's tablet components with Wong's components. Moreover, all of Wong's disclosed examples require swelling sufficient for gastric retention and Wong's use of a gastric-emptying delaying agent is solely supplementary to gastric retention due to swelling of the dosage form. For example, Wong does not disclose any dosage forms lacking swelling properties. Furthermore, at column 15, lines 29–60, Wong discloses that it is preferred to administer the "dosage forms of this invention" when "the subject is in the fed state to allow time for maximum swelling of the polymer matrix." Thus, the term "dosage form" refers to a swellable dosage form. At column 15, lines 61–65, Wong states that gastric-delaying emptying agents can be used to "facilitate retention of the dosage forms of the invention, particularly if the dosage form is to be administered to a subject in the fasted state." If the gastric-emptying delaying agent alone were sufficient to ensure gastric retention, there would be no need for other features disclosed by Wong, such as the insoluble band. Thus, the gastric-delaying emptying agents are used to suppress the housekeeping wave until the dosage form can swell adequately to be retained in the stomach.

10. The Office action also asserts that another method of gastric retention is disclosed by Wong's Figures 5–7 and at column 7, lines 53–64. Specifically, the Office action asserts that "a polymer matrix tube or ring may be provided, the ends of which would flare outwardly, resulting

in a larger effective diameter of the dosage form." However, this method still requires polymer swelling. See column 7, line 54 "swellable polymer matrix" (emphasis added) and column 7, lines 62–64,"the ends of the polymer tube or ring flaring outwardly and swelling to provide a larger effective diameter" (emphasis added). Thus, the Office action has misinterpreted the cited section of Wong as teaching a swelling independent mechanism for gastric retention. The dosage form must swell to be retained in the stomach, and must contact gastric fluid to swell.

In summary, all of Wong's disclosed embodiments swell so that the dosage form is retained in the stomach. The disclosed dosage forms would not be retained in the stomach if coated with Van Balken's coating because the polymer matrix would not contact gastric fluid and therefore would not swell.

11. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

By James W. Ayres
James W. Ayres, Ph.D.

Date 7/11/03

RESUME

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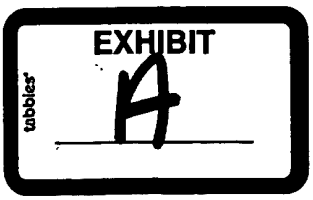
Place of Birth: Boise, Idaho; April 14, 1942

EDUCATION

Undergraduate:	Idaho State University School of Pharmacy Pocatello, Idaho	9/60 – 6/65 Approx. GPA 3.20/4.00 (Top in graduating class)
Graduate:	University of Kansas School of Pharmacy Department of Medicinal Chemistry Lawrence, Kansas 66044	9/66 – 8/70 (Mentor – Edward E. Sissman, Ph.D.)
Post-Doctoral Scientist:	Upjohn Center for Clinical Pharmacology University of Michigan Ann Arbor, MI 48109	7/76 – 7/77 (Mentor – John G. Wagner, Ph.D.)
Post-Doctoral Scientist:	Glaxo Group Research Ware, England	9/90 – 9/91
Sabbatical Leave Scientist/Consultant	Hewlett Packard Company Corvallis, OR	9/01-9/02

PROFESSIONAL AND HONORARY ORGANIZATIONS

American Association of Pharmaceutical Scientists
American Pharmaceutical Association
Academy of Pharmaceutical Sciences
American Association of Colleges of Pharmacy
Phi Lambda Upsilon Chemistry Honorary
Rho Chi Pharmacy Honorary



SELECTED PROFESSIONAL ACTIVITIES

Member Planning Committee for Western Regional APS/APhA and AAPS Meetings, 1986-1995.

National Chairman, Program Committee, Fall 1986, American Association of Pharmaceutical Sciences.

Member-at-Large, American Association of Pharmaceutical Scientists (AAPS), 1988-1991.

Vice Chair and Chair, Pharmaceutics and Drug Delivery, AAPS, 1995 and 1996.

EMPLOYMENT HISTORY

Registered Pharmacist in Idaho, Kansas and Oregon with experience as a fulltime pharmacist in each state, as well as relief work experience in each state.

Assistant Professor of Pharmaceutical Science at Oregon State University, School of Pharmacy (1970 - 1975).

Associate Professor of Pharmaceutical Science at Oregon State University, School of Pharmacy (1975 - 1981).

Professor of Pharmaceutical Science at Oregon State University, School of Pharmacy (1981 - present).

Oregon State University Distinguished Professor, Biopharmaceutics and Pharmacokinetics, College of Pharmacy (2000 to present).

AWARDS

Oregon State University Distinguished Professor (2000 to present. This is considered to be the highest award the University can bestow on a faculty member.)

Recipient 1983-present, State of Oregon Faculty Excellence Award for Research and Scholarship.

Fellow in the American Association of Pharmaceutical Scientists (1986).

Designated an Academy Fellow in the American Pharmaceutical Association Academy of Pharmaceutical Sciences (1985).

Industrial supported research (1972 - present).

Recipient of the Institute of Food Technologists Food Technology Industrial Achievement Award for outstanding advances in the applications of food technology to food production (1982).

Outstanding Young Men of America, U.S. Jaycees, 1977.
Passed doctoral preliminary examination with honors.

Visiting Professor of Pharmaceutical Education, University of Illinois School of Pharmacy at the Medical Center, Chicago, Illinois (Summer 1973).

Chosen outstanding professor of their education by the School of Pharmacy, Oregon State University graduating class of 1974.

PUBLICATIONS

1. James W. Ayres, "The Synthesis of Bicyclic Glutarimides, Bicyclic Barbituric Acids and Bicyclic Oxazoldinediones as Selective Central Nervous System Depressants, Ph.D. Thesis, University of Kansas, Lawrence, Kansas (1970).

2. Edward E. Smissman and James W. Ayres, "The Synthesis of Bicyclo (4.3.0) nonanebarbituric and -Thiobarbituric Acid Derivatives and a Bicyclo (4.4.0) decane barbituric Acid Derivative," J. Org. Chem., 36, 2407 (1971).

3. James W. Ayres, "The Synthesis of Bicyclic Glutarimides, Bicyclic Barbituric Acids and Bicyclic Oxazolidinediones as Selective Central Nervous System Depressants," Diss Abst., 31, 6490-B (1971).

4. Edward E. Smissman and James W. Ayres, "The Synthesis of 2-Keto-4a-phenyloctahydro- 'napthryridine and 2-Keto-8-methyl-7-oxa- ^{5}-1-azabicyclo (4.4.0) nonane," J. Org. Chem., 37, 1092 (1972).

5. Edward E. Smissman, James W. Ayres, Peter J. Wirth and Darrell R. Abernathy, "The Synthesis of 2,4-Diketo-3-phenyl- ^{5}-7-oxa1,5-diaza-bicyclo (4.4.0) decane," J. Org. Chem., 37, 3486 (1972).

6. James W. Ayres, Book Review of "Biopharmaceutics and Drug Interactions," by Donald E. Cadwallader, Am. J. Pharm. Ed., 36, 552 (1972).

7. James W. Ayres and Paul A. Laskar, "Student Experiments in Pharmaceutics. I.V. Additives, Chemical Incompatibilities, Kinetics, and the Arrhenius Equation," Am. J. Pharm. Ed., 38, 58, (1974).

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13. Douglass J. Stennett and James W. Ayres, "Implementation of a Practice-Oriented Parenteral Products Course," Am. J. Pharm. Ed., 40, 151 (1976).

14. James W. Ayres, Harriet Sisson and Craig Scott, "Evaluation of Self-Paced Instructional Materials in Pharmaceutics," Am. J. Pharm. Ed., 41, 11 (1977).

15. James W. Ayres, E. Sakmar, M.R. Hallmark and J.G. Wagner, "High-Pressure Liquid Chromatographic (HPLC) Determination of Tolmetin and its Major Metabolite in Plasma," Res. Comm. Chem., Path. Pharmacol., 16, 475 (1977).

16. A.V. Tembo, James W. Ayres, E. Sakmar, M.R. Hallmark and J.G. Wagner, "Plasma Prednisolone Concentrations: Comparisons of Radio-immunoassay and Competitive Protein Binding Assay," Steroids, 29, 679 (1977).

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NOTE: Page 12 contains a listing of research grants and contracts. These are not provided because many titles deal with proprietary projects funded by the drug industry.

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